Ramon Rossi Lopez
rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark S. O'Connor (011029)
moconnor@beusgilbert.com
Beus Gilbert PLLC
701 North 44th St.
Phoenix, Arizona 85008
480-429-3000

Co-Lead/Liaison Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT** (Assigned to the Honorable David G. Campbell) **(Oral Argument Requested)**

Plaintiffs Debra and James Frances Tinlin respectfully submit this response in opposition to Defendants C.R. Bard, Inc.'s and Bard Peripheral Vascular, Inc.'s ("Bard's" or "Defendant's") partial summary judgment motion (ECF 15071) ("Mot.").

I. Introduction

Deborah Tinlin is a 55-year-old woman who has lived her entire life in the state of Wisconsin. (Plaintiffs' Supplemental Statement of Facts ("SSOF") ¶¶ 4-5.) She has been married to her husband, Jim, since 1984, and she has a 28-year-old son, Andrew. (*Id.* ¶¶ 6-7.) On May 7, 2005, she was implanted with a Bard Recovery IVC filter. (*Id.* ¶ 8.)

[redacted]

[redacted]

The Recovery filter never should have been implanted in Ms. Tinlin, and she is entitled to bring her claims for Bard's negligent conduct to a jury. Bard's arguments in support of summary judgment have either been previously rejected by this Court (concerning design defect claims), or, as to other claims, require the Court to resolve plainly disputed factual issues in Bard's favor, in contravention of established summary judgment standards. The Court should deny Bard's motion in its entirety.

II. Summary Judgment Standard

Summary judgment is appropriate when no genuine issues of material fact exist. *See* Fed. R. Civ. P. 56(a). As the party seeking summary judgment, Bard "bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Evidence offered by the nonmoving party "is to be believed, and all justifiable inferences drawn in that party's favor because '[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions[.]" ECF No. 8874 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)).

III. Argument

A. Bard Has Not Carried its Burden With Respect to Warnings-Based Claims (Counts II and VII)

The parties do not dispute that a plaintiff must "establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury." *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 876 (Wis. Ct. App. 2004). The parties dispute, however, to whom a duty to warn runs and whether that threshold was met here.

1. The Learned Intermediary Doctrine Does Not Apply.

This Court has previously recognized a split of authority on the question of whether Wisconsin applies the learned intermediary doctrine. In the *Hyde* bellwether case, this Court, collecting prior authority, held that "[t]he Wisconsin Supreme Court has not decided whether to adopt the learned intermediary doctrine, and federal courts

applying Wisconsin law are split on the issue." ECF No. 12007, at 14 n.6.[1] Another Court overseeing multidistrict litigation against Bard regarding other medical devices has come to the same conclusion. *Rodenkirch-Kleindl v. C.R. Bard, Inc*., No. 2:13-CV-26026, 2016 WL 7116144, at *3 (S.D. W. Va. Dec. 6, 2016). Other Courts have declined to apply the doctrine. "The court need not and will not apply the 'learned intermediary' doctrine in this case. To echo our sister court in the Western District of Wisconsin, 'this court will not create Wisconsin law without some indication that the state's highest court would apply the doctrine if given the opportunity to do so.'" *Forst v. SmithKline Beecham Corp*., 602 F. Supp. 2d 960, 968 (E.D. Wis. 2009) (citing *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1054 (W.D. Wis. 2006)). This Court, too, should decline to apply the learned intermediary doctrine absent an express indication from the state Supreme Court that the doctrine applies in Wisconsin.

2. Ms. Tinlin Was Not Adequately Warned.

Bard does not attempt to argue, nor could it, that it adequately warned Ms. Tinlin. Ms. Tinlin was unaware of the risks and dangers of the Recovery filter. She believed she was implanted with a permanent filter. (SSOF ¶ 1.) She was told no negative information about the filter before it was placed. (*Id.* ¶ 2.) And, had she been given the choice, knowing the risks of retrievable filters, she would have chosen a permanent one. (*Id.* ¶ 3.) And, as set out in the next subsection, there is much information that her implanting doctor, Dr. Riebe, would have told her about the Recovery filter's risks, had Bard disclosed to him in the first place. (*Id.* ¶¶ 17-19; *see also infra*, section III(A)(3).)

Bard has put forward no evidence it attempted to warn Ms. Tinlin. Ms. Tinlin's testimony evidences that had she known the truth about the Recovery filter's risks, she would have chosen a permanent filter. Thus, because Bard failed to warn Ms. Tinlin of

[1] Bard continues to argue that "the weight of authority in Wisconsin" is in favor of the application of the learned intermediary doctrine. Mot. at 6. (citing *In re Zimmer, NexGen Knee Implant Products Liability Litigation*, 884 F.3d 746 (7th Cir. 2018)). But this Court was aware of *In re Zimmer* when it declined to apply the learned intermediary doctrine in *Hyde*. ECF No. 12007, at 14 (*Hyde* MSJ Ruling) (citing *Zimmer*).

any of the risks of the Recovery filter, summary judgment on the warnings-based claims should be denied.

3. Dr. Riebe Was Not Adequately Warned.

Even if the learned intermediary rule applies and Bard's duty to warn extended to the implanting physician, summary judgment is inappropriate. The law in Wisconsin is clear with respect to a duty of a device manufacturer to a practitioner. Where there is a factual dispute as to whether the manufacturer failed to disclose or "misrepresented and misled the medical community about the risks associated" with the device, summary judgment should not be granted. *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809, 817 (E.D. Wis. 2015). Summary judgment is also inappropriate if there is any indication that a *lack* of information about risks existed in the doctor's mind. *See Forst*, 602 F. Supp. 2d at 968.

A treating doctor can only warn of the risks that were known and disclosed to him by the manufacturer. That did not happen here. [redacted]

[redacted] There, the implanting doctor expressly stated that he "felt that the risks for all of the FDA-approvable devices were – were reasonable and customary" and that " … all of the devices were meeting the expectations of the FDA." ECF No. 12007, at 16 (*Hyde* MSJ Ruling, citing the implanting doctor's deposition testimony). As a result, this Court found that the plaintiff could not show that the implanting doctor "would have acted differently had he received some different warning from Bard." *Id.* at 17. Here, however, Dr. Riebe explicitly testified [redacted] Therefore, Dr. Riebe would have "acted differently in the face of different warnings by Bard," but could not have given the lack of disclosures by Bard. ECF No. 12007, at 16.

Thus, even if the learned intermediary rule applies, given that Dr. Riebe lacked information about the Recovery that he would have used and disclosed, but could not have, summary judgment on the warnings-based claims should be denied because there are genuine issues of material fact with regard to whether Dr. Riebe would have used the Recovery filter in light of that information. *See Forst*, 602 F. Supp. 2d at 968. Moreover, if he did have that information, Dr. Riebe could have switched to and used a permanent filter, such as the Cook Medical's Bird's Nest filter. (Plaintiffs' Controverting Statement of Facts ("CSOF") ¶ 5.)

B. Bard Has Not Carried its Burden on Summary Judgment with Respect to Negligent and Fraudulent Concealment Claims and Violation of Wisconsin law (Counts VIII, XII, XIII, and XIV).

Although Bard lumps them all together, not all misrepresentation claims are the same under Wisconsin law. Though Wisconsin law currently requires reliance for the Negligent Misrepresentation (count VIII) and Fraudulent Concealment (count XIII), and causation under the Wisconsin Consumer Act (count XIV), the same is not true of Plaintiffs' Fraudulent Misrepresentation claim (count XII). Regardless of whether reliance or causation is required, there are genuine issues of material fact as to Dr. Riebe's reliance on Bard's misrepresentations and omissions regarding the Recovery filter, making summary judgment inappropriate for Plaintiffs' misrepresentation claims.

[redacted] It is a more than reasonable to infer that Bard's actions caused Dr. Riebe's use of the Recovery filter and Ms. Tinlin's resulting injuries.

Bard, therefore, has failed to show that there are no genuine disputes as to misrepresentation and concealment claims here. In light of these facts, a reasonable inference in Plaintiffs' favor is that a Bard sales representative was present during Ms. Tinlin's surgery. That information never would have been noted in Ms. Tinlin's records. [redacted]

Additionally, it is reasonable to infer that, based on the connection between Dr. Riebe's mentor and Bard's affirmative representations downplaying of the risks of IVC placement in obese persons, that such information was relayed to Dr. Riebe. Both of these issues raise sufficient questions regarding misrepresentations of fact "made to a designated third person with the intention that they be communicated to the plaintiffs." *Puffer v. Welch*, 129 N.W. 525, 527 (Wis. 1911). Moreover, "proof of intent or knowledge of falsity is not required in … negligent misrepresentation claims." *Stuart v. Weisflog's Showroom Gallery, Inc*., 753 N.W.2d 448, 458 (Wis. 2012).

Unlike Plaintiff's claims for negligent misrepresentation and fraudulent concealment, fraudulent misrepresentation requires no element of reliance. "[T]o prevail on a fraudulent misrepresentation claim under Wis. Stat. §100.18, the plaintiff must show that (1) the defendants made a representation to the public with intent to induce an obligation, (2) the representation was untrue, deceptive or misleading, and (3) the representation caused him to suffer a pecuniary loss." *Andersen v. Vavreck*, No. 15-CV-667-PP, 2017 WL 680424, at *3 (E.D. Wis. Feb. 21, 2017), *aff'd*, 727 F. App'x. 870 (7th Cir. 2018) (citing *Estate of Bluma Weinstock v. ADT LLC*, No. 15–CV–1391–PP, 2016 WL 3676486, at *7 (E.D. Wis. July 7, 2016). The Wisconsin Supreme Court held "that plaintiffs in §100.18 [causes of action for fraudulent misrepresentation] do not have to demonstrate reasonable reliance as an element of the statutory claim." *Novell v. Migliaccio*, 309 Wis. 2d 132, 151 (Wis. 2008) ("neither the language of the statute, the purpose of the statute, nor the case law supports the [defendant's] argument that reasonable reliance is an element of a §100.18 cause of action"). "[A] plaintiff remains a member of 'the public' [under §100.18] unless a particular relationship exists between him or her and the defendant." *K & S Tool & Die Corp. v. Perfection Mach. Sales, Inc*., 301 Wis. 2d 109, 125 (Wis. 2007).

Thus, any and all false or misleading marketing materials, advertisements, directed to doctors or patients alike, *whether or not actually relied upon by either Ms. Tinlin or Dr.*

Riebe, are actionable under Wis. Stat. §100.18. The record is rife with examples of Bard's misleading statements to the public at large, and to doctors specifically, in that regard:

[redacted]

C. Plaintiffs' Claims for Negligent and Strict Liability Design Defects Should Proceed.

There are plainly disputed material facts at the heart of Plaintiffs' design defect claims. Bard previously and unsuccessfully moved for summary judgment on these claim in the *Hyde* case, which also involved Wisconsin law. In *Hyde*, Bard made arguments virtually indistinguishable from those asserted in this motion, and again in its Rule 50 motion, also unsuccessfully. The Court can and should reject those arguments again.

Wisconsin's product liability statute, Wis. Stat. § 895.047(1)(a), provides, "A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or voided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Plaintiffs have provided expert testimony concerning the Recovery filter's defective design and reasonable alternative designs, as well as evidence from

Bard's own data and documents concerning Bard's knowledge that the Recovery's design was defective.[2] [redacted] This Court previously held that the alternative designs that Dr. McMeeking were sufficient to satisfy Section 895.047's requirement that a plaintiff identify "an alternative design [that] would have 'reduced' the harm posed by the product," holding that the plaintiffs had "present[ed] evidence that caudal anchors help reduce filter migration, which can lead to other complications like those experienced by Mrs. Hyde (tilt, perforation, and fracture)." ECF No. 12007, at 13. Bard identifies nothing about this case that justifies a different outcome.

Bard first argues that the SNF is not a reasonable alternative design,[4] relying again, as it did in the *Hyde* case, on *Oden v. Boston Sci. Corp.*, 18-cv-0334, 2018 U.S. Dist. LEXIS 102639, at *12-13 (E.D.N.Y. Jun. 4, 2018). After acknowledging that the Court rejected this argument only months ago, Bard makes a wan attempt to distinguish Ms.

[2] *See* OSOF ¶¶ 19-26, 29, 33-42, 53-62.

[3] Contrary to Bard's statement that Dr. McMeeking had identified the SNF and "several other permanent-only filters" (Mot. at 10), this list includes both permanent and "optional" filters.

[4] Bard's parenthetical assertion (Mot. at 10) that Dr. McMeeking's identification of the SNF as an alternative design violates the Court's prior *Daubert* order is wrong. That order was clear: "The Court will not grant Defendants' motion to preclude Dr. McMeeking from opining that the SNF is a safer device than Bard retrievable filters." ECF No. 10051, at 10. The Court went on to hold that Dr. McMeeking "may not opine that the SNF would have been a safer alternative for any particular plaintiff" noting that Plaintiffs had agreed that Dr. McMeeking would not offer a medical opinion about the appropriate filter, or no filter, for any particular plaintiff. *Id.* (citing ECF No. 7806, at 20). Dr. McMeeking was and is free to opine that the SNF represents a safer design than the Recovery.

Tinlin's case on the facts, arguing that because Ms. Tinlin was not a geriatric patient, her doctor was not inclined to give her a permanent filter. Bard's attempt to draw this distinction fails, and only indicates the need for the jury to perform its fact-finding function.

In *Hyde*, the Court considered the *Oden* case and rejected Bard's attempt to draw illusory factual distinctions between permanent and retrievable filters when the filter in question – here, the Recovery – had been marketed to be both. After noting that the plaintiff in *Oden* had received a permanent filter, and that the complaint alleged that retrievable filters were not designed to be permanent, the Court held, "The evidence in this case suggests, however, that the G2 X and Eclipse filters were designed to be permanent filters, as was the SNF, and that Ms. Hyde's filter would have remained in place if it had not fractured. Whether the retrievability of the G2X and Eclipse made them sufficiently unlike the SNF to disqualify the SNF as a reasonable alternative design is a question for the jury to decide." ECF No. 12805, at 6.

Exactly the same analysis again applies here, and there is nothing about Ms. Tinlin's medical history that compels or even suggests a different result. Just like the G2 and Eclipse at issue in *Hyde*, the Recovery filter was designed to be a permanent filter, and was submitted to the FDA for clearance as a permanent device. *See* OSOF ¶ 17. Here, just as in *Hyde*,[5] the implanting physician, Dr. Riebe, [redacted] Just as in *Hyde*, whether the SNF, as a permanent filter, is a reasonable alternative design remains a fact issue.

[5] *See* OSOF ¶ 180 (noting that Ms. Hyde's physician understood that Ms. Hyde's filter could be permanent).

Ms. Tinlin's experience with the Recovery directly implicates this fact question. Having touted the Recovery's similarity to the SNF as a permanent device to gain clearance from the FDA, and then having marketed the Recovery as a permanent device to the medical community, Bard cannot now claim that retrievability is such a "key benefit" (Mot. at 12) that to remove it would be akin to "eliminating the product itself," as Wisconsin law requires in challenging an alternative design. *See Godoy v. E.I. du Pont de Nemours & Co.*, 768 N.W.2d 674, 687 (Wis. 2009) (holding that a product is not a reasonable alternative design "when some ingredients cannot be eliminated from a design without eliminating the product itself").[6]

Finally, Bard argues that "a defective product cannot be a reasonable alternative design," pointing to Plaintiffs' identification of design features incorporated into later generations of Bard filters. Mot. at 12. This argument fails. First, it ignores the Court's prior holding concerning alternative design, in which the Court found that Plaintiffs had "present[ed] evidence that caudal anchors help reduce filter migration, which can lead to other complications like those experienced by Mrs. Hyde (tilt, perforation, and fracture)." ECF No. 12007, at 13. The relevant question under Wisconsin law is, as the Court recognized, whether "the foreseeable risks of harm posed by the product could have been reduced or voided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). Plaintiffs have done that, identifying features that reduce the risk of harm. Bard's argument that Dr. McMeeking has identified alternative designs that are part of other defective Bard filters also ignores his identification of other filters as alternative designs, including the Greenfield filter.

[6] In addition to citing cases from outside of Wisconsin for the proposition that the SNF is not an alternative design (Mot. at 11-12), Bard again relies on *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760 (Tex. App. 2009), a case involving oral contraceptives, and that this Court held was not apposite, noting that the "proposed alternative would have removed a key ingredient." ECF No. 12805, at 6.

D. Any Summary Judgment Motion on Loss of Consortium Is Premature.

Bard also asks the Court to grant summary judgment on Mr. Tinlin's claim for loss of consortium if Ms. Tinlin's claims are dismissed. Plaintiffs agree that a loss of consortium claim is derivative of Ms. Tinlin's claims. The Court can reach that claim if necessary, but for the reasons stated above, Ms. Tinlin's claims should reach trial.

E. Plaintiffs' Experts Testified to Future Damages With the Required Level of Certainty.

Bard's final argument, that Plaintiffs' experts cannot testify to the probability of future complications (Mot. at 13), misstates Plaintiffs' experts' testimony and misapplies it to Wisconsin law. As this Court has recognized, under Wisconsin law, a plaintiff seeking damages for future injury must establish such damages to a medical probability. *See* ECF No. 12805, at 5 (citing *Bleyer v. Gross*, 120 N.W. 2d 156, 160 (Wisc. 1963)). Both experts testified to the risk of Ms. Tinlin experiencing future complications due to her failed filter to a medical probability, satisfying this standard. Bard never directly quotes any of Dr. Muehrcke's or Dr. Hurst's deposition testimony to support its assertion that neither expert testified that Ms. Tinlin would "probably" suffer certain complications, and points to no quotation from either that Ms. Tinlin's future damages are a "mere possibility."

[redacted]

[redacted] None of these opinions concerning future complications are stated as "mere possibilities."

IV. Conclusion

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Bard's motion.

Dated: March 1, 2019

BEUS GILBERT PLLC

By: */s/ Mark S. O'Connor*
Mark S. O'Connor
701 North 44th St.
Phoenix, Arizona 85008

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liaison Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of March, 2019, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine